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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,997	10/12/2000	Olivier De Lacharriere	196726US0	5836

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EXAMINER

WILLIS, MICHAEL A

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 12/12/2001

6

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/686,997	<b>Applicant(s)</b> DE LACHARRIERE ET AL.	
	<b>Examiner</b> Michael A. Willis	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some    \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Applicant's amendment of 30 October 2001 is entered. Claims 1-35 are pending. Any previous rejections that are not restated in this Office Action are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Response to Arguments***

Claims 1-35 are rejected under 35 USC 112, second paragraph as follows:

Claims 1-2, 5-7, 9-13, 16-18, 20-24, 27-29, and 31-34 are rejected under 35 USC 112, second paragraph, due to the term "derivative" for reasons as set forth in a previous Office Action. Applicant asserts that the specification describes in detail the types of compounds which are metabolic derivatives of DHEA at page 5, lines 18-20. Applicant argues that the description provides a standard for ascertaining which compounds are derivatives. However, the cited passage provides a list of three compounds as examples of metabolic derivatives of DHEA and specifically states "without this list being limiting". It is the position of the examiner that one of ordinary skill in the art would not be apprised of whether or not the limitation of metabolic "derivatives" includes such compounds as testosterone, estriol, or other metabolites of DHEA. Additionally, the standard for ascertaining other claimed derivatives, i.e. sugar derivatives, arbutin derivatives, benzophenone derivatives, cinnamic acid derivatives, triazine derivatives, etc., is not provided.

Any remaining claims are rejected for depending from indefinite base claims.

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Claims 1 and 2 are rejected under 35 USC 102(b) as being anticipated by Hadley *et al* for reasons as stated in a previous Office Action. Applicant argues that Hadley describes topical application of estrogens, but that DHEA is not an estrogen. Examiner agrees that DHEA is not an estrogen. However, it is noted that the claims are drawn to DHEA or at least one biological precursor thereof **or a metabolic derivative thereof**. It is the position of the examiner that estrogens are metabolic derivatives of DHEA. For example, estriol, estradiol-17 $\beta$ , and estrone are all estrogens that are metabolites of DHEA. Therefore, the reference anticipates the claims.

Claims 1-35 are rejected under 35 USC 103(a) as being unpatentable over Hadley *et al* in view of Breton *et al* for reasons as stated in a previous Office Action.

Applicant argues that Hadley only teaches that manipulation of systemic levels of androgens affects melanin production. Applicant states "For example, Hadley et al discuss the effects of castrating rats or "administration of an androgen" on the pigmentation of rats, the effects of "androgen excess" on human female pigmentation, and the effects of "testosterone implants" on male golden hamster pigmentation." Applicant argues that Hadley fails to describe the topical administration of androgens to control pigmentation. The examiner agrees that Hadley does not specifically teach topical administration of androgens, but rather teaches "administration of an androgen" in a general way that in no way excludes or teaches away from topical administration. Therefore, one of ordinary skill in the art is motivated to find appropriate modes of

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administration of androgens such as the topical formulations as found in Breton in order to practice the methods taught by Hadley.

Applicant argues that Breton fails to describe compositions for the purpose of controlling pigmentation marks, and that Breton only describes the topical application of S-DHEA compositions for cutaneous aging, treating wrinkles and fine lines, and for firming skin tissue. Therefore, applicant argues that Breton fails to recognize that S-DHEA could be useful in compositions for regulating pigmentation. While it is noted that Breton also teaches compositions of S-DHEA for "reviving the radiance of the skin" (see col. 2, lines 1-12), the examiner agrees that Breton by itself does not render obvious the claimed subject matter. Rather, it is the combination Hadley in view of Breton that yields the current claims unpatentable.

Therefore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

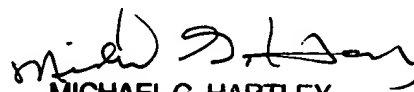
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L. Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

  
Michael A. Willis  
Examiner  
Art Unit 1619

December 5, 2001

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER